



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,464	10/16/2001	Frank L. Graham	ADVEC101A-C1	5099
29847	7590	04/20/2004	EXAMINER	
BEUSSE BROWNLEE WOLTER MORA & MAIRE 390 N. ORANGE AVENUE SUITE 2500 ORLANDO, FL 32801			VOGEL, NANCY S	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/978,464

Applicant(s)

GRAHAM ET AL.

Examiner

Nancy T. Vogel

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 and 31-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 and 31-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

Claims 1-28 and 31-34 are pending in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Arguments***

Applicant's arguments, see pages 15-16 of the response, filed 1/26/04, with respect to rejections under 35 USC 102(b), have been fully considered and are persuasive. The rejections under 35 USC 102(b) have been withdrawn.

### ***Double Patenting***

Claims 1-28 and 31-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,379,943. Although the conflicting claims are not identical, they are not patentably distinct from each other because they contain limitations which overlap, or the claims recite overlapping groups of plasmids, or other specific nucleic acid sequences. Further, the plasmids or nucleic acid sequences are used for the same purpose: construction of infectious adenovirus vectors. The claims of the prior US patent recite a method for making an infectious adenovirus which comprises a first nucleic acid sequence encoding adenovirus sequences which in the absence of intermolecular recombination are insufficient to encode an infectious, replicable or packageable virus and a second nucleic acid sequence which in the absence of

Art Unit: 1636

intermolecular recombination are insufficient to encode an infectious, replicable or packageable virus, each containing a site-specific recombinase recognition target site. The present claims differ in that they require head to head ITR junctions. Although not specifically claimed in the prior US patent, the claims of the prior patent embrace the instant claims because they provide for the efficient and reliable isolation of viral vectors using recombinase pathways. The methods of the prior patent embrace the instant claims because plasmids used in the prior patent do contain head to head ITRs such that the instant claims are an obvious variation on the prior claims.

This rejection is maintained for reasons made of record in the previous Office action, mailed 10/21/03. Applicant has stated that in their remarks submitted 1/26/04, that they will provide a terminal disclaimer upon notification of allowance of claims, and further, that the conflicting referenced patent is commonly owned with the present application (page 12 of remarks).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 9, 14, 17, 18, 24, 25, 28, 30, 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is maintained for reasons made of record in the previous Office action, mailed 10/21/03. Applicant's arguments filed 1/26/04 have been fully considered but they are not deemed to be persuasive. Applicants have argued that some of the precursor plasmids used to construct the claimed plasmids are currently available commercially. However, such a commercial source may become unavailable. Furthermore, since applicant states that "some precursor plasmids are currently available commercially" (page 13 of reply), it is presumed that some of the precursor plasmids are not available from any source. Therefore, it is maintained that the rejected claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. In order to sufficiently enable the claims, applicant must make a biological deposit of each recited plasmid. The deposit rules pursuant to 37 CFR 1.801-1.809 set forth examining procedures and conditions of deposit which must be satisfied when a deposit is required. See MPEP 2402-2404.

***Claim Rejections - 35 USC § 112***

Claims 9, 11, 14, 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained essentially for the reasons made of record in the previous Office action, mailed 10/21/03, and slightly altered to take into consideration applicant's amendment to the claims filed 1/26/04. Applicants have amended the claims to remove the phrase "which, as optionally needed, undergo additional modification to provide a head-to-head ITR junction". However, it is noted that at least some of the recited plasmids do not appear to have a head-to-head ITR junction, which is a requirement recited in the claim on which the rejected claims depend, i.e. claims 1, 10, and 16. Therefore, the rejected claims are confusing and indefinite and fail to distinctly claim the subject matter which applicant regards as the invention.

### ***Conclusion***

**No claims are allowed.**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

4/14/04

  
TERRY MCKELVEY  
PRIMARY EXAMINER